

## REMARKS

### **1. Interview Summary**

Applicants graciously acknowledge that the Examiner granted an interview on December 4, 2007. Proposed amendments to the claims were discussed. However, no agreement was made at that time. As requested, the proposed amendments to the claims are being submitted herein along with remarks.

### **2. Claim Rejections – 35 U.S.C. § 102**

In the Office Action mailed September 20, 2007, claims 21 and 25-28 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,885,227 to Finlayson. Applicants respectfully traverse these rejections.

#### **A. Claims 21 and 25**

Independent claim 21 as amended recites “an elongate member comprising a proximal end, a main body having a first diameter, a distal tip portion comprising an elongate tip having a uniform second diameter, and a single taper portion disposed directly between the main body and distal tip portion and defining a taper between the first and second diameters.” Figures 1-4 of Finlayson do not disclose an elongate member with a single taper positioned between a main body and a distal tip portion.

Claim 21 as amended also recites “the length of the flexible tip axially extending beyond the elongate tip of the distal tip portion being greater than a longitudinal length of the elongate tip of the distal tip portion.” Finlayson discloses that the “plastic tip extends slightly beyond the flattened end 12d of the core 12, to form the bumper 24.” Col. 4, lines 46-49. However, Finlayson does not disclose a flexible tip with a length longer than an elongate tip of a distal tip portion of an elongate member. Accordingly, Applicants respectfully submit that the rejection to claim 21 has been overcome.

Claim 25 depends upon claim 21 and should be allowable at least for the same reasons. Additionally, claim 25 as amended recites “the length of the flexible tip that extends beyond the elongate tip of the distal tip portion is greater than 3 mm.” The cited portions of Finlayson do not disclose a length of the “bumper 24.”

**B. Claims 26 and 27**

Independent claim 26 as amended recites “a length by which the flexible tip extends distally beyond the elongate tip of the distal tip portion of the elongate member being approximately equal to or greater than a longitudinal length of the elongate tip of the distal tip portion.” The portions of Finlayson relied upon by the Office Action do not disclose a flexible tip extending distally beyond a distal tip portion of an elongate member by a length equal to or greater than the length of an elongate tip of the distal tip portion of the elongate member. Accordingly, Applicants respectfully submit that the rejection to claim 26 has been overcome. Claim 27 depends upon claim 26 and should be allowable for at least the same reasons.

**3. Claim Rejections – 35 U.S.C. § 103**

In the Office Action, claims 1-28 were rejected under 35 U.S.C. § 103(a) as being anticipated by U.S. Patent Application No. 2004/0087876 to Eskuri in view of U.S. Patent No. 5,303,714 to Abele et al. Applicants respectfully traverse these rejections.

Eskuri is directed toward an outer member enclosing a number of balls. Abstract. On the other hand, Abele et al. is directed toward an outer sleeve that is slid over a main body and butts against the proximal end of an enlarged tip portion. Abstract. The outer sleeve of Abele et al. contributes to the axial stiffness of the device to enable manipulation of the guidewire through an occlusion. Abstract. Therefore, Applicants respectfully submit

that one skilled in the art would not look to combine Eskuri with Abele et al., and then drastically alter that combination to reach the embodiments of the present Application.

Furthermore, since the time that the Office Action was mailed, the new *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526 (Oct. 10, 2007) have been issued. The new Examination Guidelines state that “the key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn* stated that ‘[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’” 72 Fed. Reg. 57528, col. 3 – 57529, col. 1. Therefore, Applicants respectfully submit that the Office Action’s conclusory statements that one skilled in the art would have combined Eskuri and Abele et al. “to achieve a desired flexibility at the distal tip” are legally deficient. For instance, as noted herein, Abele et al. is primarily directed toward providing an outer sleeve, and does not disclose a “flexible tip,” as recited by the pending claims, that extends distally beyond an elongate tip of a distal tip portion of an elongate member. Accordingly, Applicants respectfully submit that the obviousness rejections have been overcome for the above reasons alone.

**A. Claims 1-13**

Additionally, independent claim 1 as amended recites “a coating disposed on the distal end and secured to the elongate tip having the second uniform diameter of the distal end, the coating comprising a solid flexible tip having a length axially extending beyond

the elongate tip of the distal end of the elongate member in the distal direction, the solid flexible tip is made from primarily biocompatible material and forms a distal end portion of the guidewire having a flexible and solid structure.” Eskuri relates to an outer member enclosing a number of balls. Eskuri discloses two embodiments for the outer member, an inner lumen (*see, e.g.*, Figures 1, 3, and 5; Para. 0024) and a coil (*see, e.g.*, Figures 2, 4, and 6; Para. 0031) – neither of which is the solid and flexible tip recited by claim 1.

Claim 1 as amended also recites “the length of the solid flexible tip that extends axially beyond the elongate tip of the distal end being approximately equal to or greater than a longitudinal length of the elongate tip of the distal end.” Eskuri does not disclose a longitudinal length of an elongate tip of a distal end. Therefore, Eskuri cannot disclose a solid flexible tip that extends beyond an elongate tip of a distal end of an elongate member by a length of the elongate tip.

Claim 1 as amended further recites “the ratio of (a) the length of the solid flexible tip that extends axially beyond the elongate tip of the distal end to (b) the first uniform diameter of the main body of the elongate member being greater than 3:1.” Eskuri does not disclose a ratio of (1) the length of the solid flexible tip that extends beyond the elongate tip to (2) the diameter of the main body that is greater than 3:1. Rather, Para. 0020 of Eskuri only discloses a length of a distal portion of a shaft 14, not a length of an elongate tip of a distal portion of a shaft or a length of a solid flexible tip that extends beyond an elongate tip of a distal portion.

Abele et al. does not cure the deficiencies identified above. Therefore, Applicants respectfully submit that the rejection to claim 1 has been overcome. Claims 2-13 depend upon independent claim 1 and should be allowable for at least the same reasons.

**B. Claims 14-20**

Independent claim 14 as amended recites a coating having “a coating disposed on at least the elongate tip of the distal tip portion of the elongate member and comprising a flexible and solid tip of primarily biocompatible material that is located at a distal end of the guidewire, the flexible and solid tip having a second length axially extending beyond the first length of the elongate tip of the distal tip portion of the elongate member, the second length of the flexible and solid tip being approximately equal to or greater than the first length of the elongate tip of the distal tip portion of the elongate member.” For at least the same reasons as stated above with respect to independent claim 1, Applicants respectfully submit that the rejection to claim 14 has been overcome. Claims 15-20 depend upon independent claim 14 and should be allowable for at least the same reasons.

**C. Claims 21-25**

Independent claim 21 as amended recites “the polymer coating comprising a flexible tip of solid composition having a length axially extending beyond the elongate tip of the distal tip portion.” Claim 21 as amended also recites “the length of the flexible tip axially extending beyond the elongate tip of the distal tip portion being greater than a longitudinal length of the elongate tip of the distal tip portion.” For at least the same reasons stated above with respect to independent claim 1, Applicants respectfully submit that the rejection to claim 21 has been overcome. Claims 22-25 depend upon claim 21 and should be allowable for at least the same reasons.

**D. Claims 26-28**

Independent claim 26 as amended recites “the coating comprising a flexible tip of substantially polymeric material and having a solid internal structure that (1) extends distally beyond the elongate tip of the distal tip portion.” Claim 26 as amended also

recites "a length by which the flexible tip extends distally beyond the elongate tip of the distal tip portion of the elongate member being approximately equal to or greater than a longitudinal length of the elongate tip of the distal tip portion." For at least the same reasons stated above with respect to independent claim 1, Applicants respectfully submit that the rejection to claim 26 has been overcome. Claim 27 depends upon claim 26 and should be allowable for at least the same reasons.

### **SUMMARY**

Applicants respectfully submit that all of the pending claims are in condition for allowance and seek allowance thereof. If for any reason the Examiner is unable to allow the Application but believes that an interview would be helpful to resolve any issues, the Examiner is respectfully requested to call the undersigned at (312) 321-4277.

Respectfully submitted,

/Timothy J. Le Duc/  
Timothy J. Le Duc  
Registration No. 54,745  
Attorney for Applicants

BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, ILLINOIS 60610  
(312) 321-4200

Dated: December 5, 2007